

APR 22 1997

K97 0394

Osteonics® Normalized AD-HA Acetabular Component System

510(k) Summary

**510(k) Premarket Notification
Summary of Safety and Effectiveness
for the
Osteonics® Normalized AD-HA Acetabular Component System**

Submission Information

Name and Address of the Sponsor
of the 510(k) Submission:

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Contact Person:

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Date of Summary Preparation:

January 31, 1997

Device Identification

Proprietary Name:

Osteonics® Normalized AD-HA
Acetabular Component System

Common Name:

Artificial Acetabular Component

Classification Name and Reference:

Hip Joint Metal/Ceramic/Polymer
Semi-Constrained Cemented or
Non-Porous Uncemented Prosthesis
21 CFR §888.3353

Predicate Device Identification

The Osteonics® Normalized AD-HA Acetabular Components are substantially equivalent to the following competitive and/or Osteonics devices, which have previously been determined substantially equivalent by FDA:

- Osteonics® Secur-Fit™-HA PSL® X'tra Acetabular Component System: Osteonics Corporation.

Device Description

The Osteonics® Normalized AD-HA Acetabular Components are single-use devices. Each Osteonics® Normalized AD-HA Acetabular Component consists of two pieces: an Osteonics® Normalized AD-HA Acetabular Shell and an Osteonics® Omnifit® Scalloped Cup Insert. The metal shell is intended for cementless fixation within the prepared acetabulum.

The Osteonics® Normalized AD-HA Acetabular Shells are characterized by the following features:

- A basic spherical and tangent radii design.
- The predicate interior geometry which allows a mating polyethylene insert size to be used with more than one shell size.
- Peripheral screw holes.
- A dome hole which is compatible with the optional, currently marketed Osteonics® Acetabular Dome Hole Plugs.
- Circumferential normalizations.
- A wide range of sizes.
- One of two screw hole configurations:
 - 6 peripheral screw holes and no dome screw holes,
 - 6 peripheral screw holes, and 5-7 dome screw holes.
- Osteonics' AD-HA coating.

The Osteonics® Omnifit® Scalloped Cup Inserts differ from the predicate Osteonics® Omnifit® Cup Inserts in that they feature a scalloped rim. The scalloped rim allows for clearance between bone screws (which may be placed in the peripheral screw holes of the shell) and the insert's rim.

Intended Use:

The Osteonics® Normalized AD-HA Acetabular Components are single-use devices. The shells are intended for cementless fixation within the prepared acetabulum. The Osteonics® Normalized AD-HA Acetabular Components are compatible with any appropriately selected Osteonics hip stem/femoral head combination.

Indications:

The indications for the use of the Osteonics® Normalized AD-HA Acetabular Components, in keeping with those of other legally marketed Osteonics acetabular components, are as follows:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Statement of Technological Comparison:

The substantial equivalence of the Osteonics® Normalized AD-HA Acetabular Components to the predicate devices identified above—in terms of intended use, materials, and design features—is based on the following.

Intended Uses:

The Osteonics® Normalized AD-HA Acetabular Components, like the predicate acetabular components cited above, are intended for cementless fixation. The subject devices and the predicate devices share the same indications for use.

Materials:

The Osteonics® Normalized AD-HA Acetabular Shells and the predicate acetabular shells cited above are manufactured from the same materials. Both devices have a shell substrate machined from ASTM F-67 CP Titanium. Both devices feature Osteonics' AD-HA coating (arc-deposited CP Ti, beneath plasma-sprayed hydroxylapatite).

The Osteonics® Omnifit® Scalloped Cup Inserts and the predicate Osteonics® Omnifit® Cup Inserts are both manufactured from ultra-high molecular weight polyethylene, and feature a locking wire made from cobalt chromium alloy.

Design:

The Osteonics® Normalized AD-HA Acetabular Shells differ from the predicate Osteonics Secur-Fit™-HA PSL® X'tra Acetabular Components as follows:

- The subject acetabular shells feature 6 peripheral screw holes; whereas the predicate devices feature from 6 - 8 peripheral screw holes.
- The peripheral screw holes of the subject shell are completely enclosed within the shell rim; whereas the peripheral screw holes of the predicate shell "break out" from the shell rim.
- The outer geometry of the subject devices features a hemispherical, tangent radii design, whereas the outer geometry of the predicate devices features Osteonics' Dual Radius geometry.

The Osteonics® Omnifit® Scalloped Cup Inserts differ from the predicate Osteonics® Omnifit® Cup Inserts in that they feature a scalloped rim.

None of these design differences raises any new questions of safety or effectiveness.

Summary

Based on the similarities presented above, the supporting testing reproduced in Appendix C, the pre-clinical data incorporated by reference to prior submissions, and the fact that the Osteonics®

Normalized AD-HA Acetabular Components employ standard sterilization and packaging methods, the substantial equivalence of the Osteonics® Normalized AD-HA Acetabular Components to other legally marketed, class II, acetabular components is demonstrated.

Performance Data:

A complete battery of tests, in accordance with the following FDA guidelines, was conducted to qualify and characterize the AD-HA coating of the subject devices: FDA's "Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants, November 11, 1992" and FDA's "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement, April 28, 1994."